

#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

#### NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

01/11/2002

EDMUND J SEASE ZARLEY MCKEE THOMTE VOORHEES & SEASE 801 GRAND AVENUE SUITE 3200 DES MOINES, IA 50309 EXAMINER
HOWARD, SHARON LEE

ART UNIT CLASS-SUBCLASS

1615 424-497000

DATE MAILED: 01/11/2002

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/437.449	11/10/1999	VIJAY KUMAR	P04176US0	7991

TITLE OF INVENTION: PALATABLE, SUSTAINED RELEASE DRUG GRANULES

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	· ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
14	nonprovisional	YES	\$640	\$0	\$640	04/11/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>, THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY

A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

□ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

Complete and mail this form, together with applicable fee(s), to:

**Box ISSUE FEE** 

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

01/11/2002

**EDMUND J SEASE** ZARLEY MCKEE THOMTE VOORHEES & SEASE 801 GRAND AVENUE SUITE 3200 DES MOINES, IA 50309

Note: The certificate of mailing below can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Certificate of Mailing
I hereby certify that this Fee(s) Transmittal is being deposited with the
United States Postal Service with sufficient postage for first class mail in an
envelope addressed to the Box Issue Fee address above on the date
indicated below.

materica below.	
	(Depositor's name)
	(Signature)
	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/437.449	11/10/1999	VIJAY KUMAR	P04176US0	7991

TITLE OF INVENTION: PALATABLE, SUSTAINED RELEASE DRUG GRANULES

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
14	nonprovisional	YES	\$640	\$0	\$640	04/11/2002
EXA	MINER	ART UNIT	CLASS-SUBCLAS	ss		
HOWARD,	SHARON LEE	1615	424-497000	<b>_</b>		
1. Change of correspon CFR 1.363). Use of PT but not required.	dence address or indica O form(s) and Custome	tion of "Fee Address" (37 r Number are recommende	ale maines of up t	the patent front page, lie o 3 registered patent atto- ternatively, (2) the name	omeys 1	
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.			single firm (havi	ng as a member a regi ) and the names of up	stered to 2	
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.			registered patent a is listed, no name	ttorneys or agents. If no will be printed.	name 3	

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment. (B) RESIDENCE: (CITY and STATE OR COUNTRY) (A) NAME OF ASSIGNEE

Please check the appropriate assignee category or catego	ries (will not be printed on the patent)	<b>⊔</b> individual	☐ corporation or other private group	entity U government		
4a. The following fee(s) are enclosed:	4b. Payment of Fee(s):					
☐ Issue Fee	☐ A check in the amount	☐ A check in the amount of the fee(s) is enclosed.				
☐ Publication Fee	☐ Payment by credit care	☐ Payment by credit card. Form PTO-2038 is attached.				
☐ Advance Order - # of Copies	☐ The Commissioner is I Deposit Account Number	☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number(enclose an extra copy of this form).				
The COMMISSIONER OF PATENTS AND TRADEM application identified above.	ARKS is requested to apply the Issue Fee	and Publication	Fee (if any) or to re-apply any previous	sly paid issue fee to the		
(Authorized Signature)	(Date)			*********		
NOTE; The Issue Fee and Publication Fee (if require other than the applicant; a registered attorney or againterest as shown by the records of the United States Pa Burden Hour Statement: This form is estimated to take depending on the needs of the individual case. Any cord to complete this form should be sent to the Chief Infand Trademark Office, Washington, D.C. 20231. DO FORMS TO THIS ADDRESS. SEND FEES AND Assistant Commissioner for Patents, Washington, D.C.	ent; or the assignee or other party in tent and Trademark Office.  10.2 hours to complete. Time will vary ments on the amount of time required ormation Officer, United States Patent NOT SEND FEES OR COMPLETED THIS FORM TO: Box Issue Fee,					
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.						



#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.usqutu.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/437,449	09/437,449 11/10/1999 VIJAY KUMAR		P04176US0	7991
75	90 01/11/2002		EXAMIN	ER .
EDMUND J SEA	<del></del>	FS & SFASF	HOWARD, SHARON LEE	
ZARLEY MCKEE THOMTE VOORHEES & SEASE 801 GRAND AVENUE SUITE 3200			ART UNIT	PAPER NUMBER
DES MOINES, IA	50309		1615	
			ATE MAILED: 01/11/2002	

# Determination of Patent Term Extension under 35 U.S.C. 154 (b) (application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)



## Notice of Allowability

Application No.

Applica 09/437,449

Vijay Kumar

1615

Examiner

**Sharon Howard** 

Art Unit



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate of Allowability IS NOT A GRANT OF PATENT RIGHTS. The initiative of the Office or upon petition by the applicant. See 37 CFR 1.3	propriate communication will be mailed in due course. This application is subject to withdrawal from issue at					
1. $\blacksquare$ This communication is responsive to <u>12/3/2001</u> .						
2. X The allowed claim(s) is/are <u>1, 2, 4-9, 11-14, 16, and 33</u>						
3. X The drawings filed on Nov 10, 1999 are acceptable as for	ormal drawings.					
4. Acknowledgement is made of a claim for foreign priority under 3	5 U.S.C. § 119(a)-(d).					
a) $\square$ All $\square$ b) $\square$ Some* c) $\square$ None of the:						
1.   Certified copies of the priority documents have been received.	ved.					
2. Certified copies of the priority documents have been received	ved in Application No					
<ol> <li>Copies of the certified copies of the priority documents had application from the International Bureau (PCT Rule 17.</li> </ol>	ve been received in this national stage 2(a)).					
*Certified copies not received:	·					
5.   Acknowledgement is made of a claim for domestic priority under	35 U.S.C. § 119(e).					
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communoted below. Failure to timely comply will result in ABANDONMENT of this EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTIT for samplying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL I	application. THIS THREE-MONTH PERIOD IS NOT TUTE OATH OR DECLARATION. This three-month period					
6. Note the attached EXAMINER'S AMENDMENT or NOTICE OF IN reason(s) why the oath or declaration is deficient. A SUBSTITUTE	FORMAL APPLICATION (PTO-152) which gives JTE OATH OR DECLARATION IS REQUIRED.					
7. Applicant MUST submit NEW FORMAL DRAWINGS						
(a) $\square$ including changes required by the Notice of Draftsperson's Pa	atent Drawing Review (PTO-948) attached					
1) $\square$ hereto or 2) $\square$ to Paper No						
(b) including changes required by the proposed drawing correction approved by the examiner.	on filed, which has been					
(c) including changes required by the attached Examiner's Amen Paper No	dment/Comment or in the Office action of					
Identifying indicia such as the application number (see 37 CFR 1.84 drawings should be filed as a separate paper with a transmittal lette	(c)) should be written on the drawings. The raddressed to the Official Draftsperson.					
8. Note the attached Examiner's comment regarding REQUIREMENT	T FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.					
Any reply to this letter should include, in the upper right hand corner, t NUMBER). If applicant has received a Notice of Allowance and Issue Fe the NOTICE OF ALLOWANCE should also be included.	he APPLICATION NUMBER (SERIES CODE/SERIAL ee Due, the ISSUE BATCH NUMBER and DATE of					
Attachment(s)						
1 Notice of References Cited (PTO-892)	2 Notice of Informal Patent Application (PTO-152)					
3 Notice of Draftsperson's Patent Drawing Review (PTO-948)	4 ☐ Interview Summary (PTO-413), Paper No 6 ☐ Examiner's Amendment/Comment					
5 🗶 Information Disclosure Statement(s) (PTO-1449), Paper No(s) 7 🔲 Examiner's Comment Regarding Requirement for Deposit of Biological	8 X Examiner's Statement of Reasons for Allowance					
Material	20.00					
9 Other	Supervey Cy Capate Summer					

Application/Control Number: 09/437,449 Page 2

**Art Unit: 1615** 

### Allowable Subject Matter

1. The following is an examiner's statement of reasons for allowance: The prior art does not teach or suggest the teachings of a polymer complex for entrapping drug granules comprising a complex of polyvinyl acetate phthalate (PVAP); and polyvinylpyrrolidone (PVP); said PVAP-PVP complex having bands at about 1657 cm<sup>-1</sup> and 1724 cm<sup>-1</sup> in the spectrum of the PVAP-PVP complex as now claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Howard whose telephone number is (703) 308-4359. The examiner can normally be reached Monday through Friday from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 308-7924.

Application/Control Number: 09/437,449

Art Unit: 1615

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

**Sharon Howard** 

December 27, 2001

Sharon Howard

THURMAN & PAGE

Page 3